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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PENG, BO	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,354	VAN DER WERF ET AL.	
	Examiner	Art Unit	
	BO PENG	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *1,3-27, 30 and 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,28 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *6/2/06* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/12/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *attachment*.

DETAILED ACTION

1. The preliminary amendment filed on March 26, 2009, is acknowledged. Claims 1-31 are pending. Claims 5-20, 30 and 31 have been withdrawn.

Restriction Election

2. Applicants' election, with traverse, of Group I (Claims 1-4, 28 and 29), and species election, with traverse, of polypeptide consisting of 1-1193 amino acids of SEQ ID NO: 3 (species 3), in the reply filed on March 26, 2009, is acknowledged.

3. Applicant traverses the restriction requirement on the grounds that the monoclonal antibody of Claim 21 (Group III) should be examined with the elected polypeptide as the protein or polypeptide is recognized by the claimed antibody. The method Claims 22 to 25 (Group VI and VII), which relate to the use of the protein or polypeptide, should be examined with the elected invention. At least, these claims should be rejoined with the elected claims once the elected claims are found to be allowable. Further, the immune complex of Claims 26 and 27 (Group VIII) should be examined with the elected invention, since the immune complex contains the protein or polypeptide of the election invention.

4. Applicant's arguments have been considered, but are not persuasive. As indicated in *Restriction*, Group I, III, VI, VII and VIII are not related to a single general inventive concept under PCT Rule 13.1 because, under PCT rule 13.2, they lack the same or corresponding special technical features. The technical feature of Group I, which is directed to SARS spike (S) protein, cannot be a special technical feature under PCT Rule 13.2 because the technical feature is shown in the prior art. Marra teaches SARS spike

protein and its sequence (Science. 2003 May 30; 300(5624):1399-404). Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art, the subject matters of Groups I, III, VI, VII and VIII do not have a single general inventive concept, and so lack unity of invention. Therefore, the restriction is proper. Regarding the requested rejoinder of method Claims 22 to 25 (Groups VI and VII), where the elected product claims of Group I are subsequently found allowable, the method of using the allowable product will be considered for rejoinder in accordance with the provisions of MPEP § 821.04. See *Restriction* Para 14 and 15.

5. Applicant further traverses the election of species on the ground that a search of the prior art for SEQ ID NO: 3 would necessarily disclose each species (3), (4) and (5), because all of these species are derived from SEQ ID NO: 3.

6. This is also not found persuasive because the polypeptides **consisting of** amino acids 1-1193, 14-1193 and 475-1193 of SEQ ID NO: 3 are distinct and divergent. The search for these sequences is not co-extensive. According to PCT Rule 13.2 and the guidelines in Section (f)(i)(B)(1) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common structure which is a significant structural element. Although Species (3), (4) and (5) are derived from SEQ ID NO: 3, they are not regarded as being of a similar nature because the shared common structural element is not significant. The requirement is still deemed proper and is therefore made FINAL.

7. Accordingly, Claims 1, 3, 4 and 21-27 are withdrawn from further consideration by the Examiner, under 37 C. F. R. 1.142(b), as being directed to a nonelected invention. Claims 2, 28 and 29 are examined in this Office action.

Foreign Priority

8. Applicant's provision of foreign priority documents France 0314152, filing date December 2, 2003; and France 0314151, filing date December 2, 2003, is acknowledged. It is noted, however, that English translation of the foreign priority documents have not been provided. Applicant is reminded that such priority for the claimed inventions requires support of written description and enablement under 35 U.S.C. 112, first paragraph, in the priority document. Since the English translation of the foreign priority document has not been provided, it is not clear whether the document provides a written description for the instant claims. Therefore, the priority date is deemed to be December 2, 2004, the filing date of the PCT/FR04/03105.

Information Disclosure Statement

9. The information disclosure statement submitted on April 12, 2007, is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Specification

10. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, See Para [0540], for example. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP §608.01.

Claim Objection

11. Claim 2 is objected to because it depends on the withdrawn Claim 1. Claim 28 is objected to for containing a non-elected invention of "an antibody claimed in Claim 21". Correction is required.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claim 29 is rejected under 35 U.S.C. 102(e) as being anticipated by Vilalta *et al.* (US 20070105193, Provisional application 60/482505, filing date June 26, 2003).

14. Claim 29 reads on an immunogenic composition **comprising** a recombinant protein or polypeptide of Claim 2.

15. Vilalta *et al* teach a composition comprising polypeptide of the S protein of SARS-CoV Urbani strain, wherein the peptide of SEQ ID NO: 2 consists of amino acids 1-1196 of S protein, see e.g. [0015] and Claims 435 and 450. The polypeptide of SEQ ID NO: 2 comprises the claimed polypeptide consisting of 1-1193 of S protein, see attached sequence alignment. The peptide of SEQ ID NO: 2 was disclosed at least in Provisional Application 60/482505, filing date June 26, 2003. In view of this teaching, Claim 29 is anticipated by Vilalta.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claims 2, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vilalta *et al.* (US 20070105193, Provisional application 60/482505, filing date June 26, 2003).

18. Vilalta *et al* teach a polypeptide of the S protein of SARS-CoV Urbani strain, wherein the peptide of SEQ ID NO: 2 consists of amino acids 1-1196 of the S protein, see e.g. [0015] and Claims 435 and 450. The polypeptide of SEQ ID NO: 2 comprises the claimed polypeptide consisting of 1-1193 of S protein, see attached sequence alignment. Vilalta characterizes S protein, of which amino acids 1 to about 1195 comprise an extracellular domain; amino acids from about 1196 to about 1218 are part of a transmembrane domain; and amino acids from about 1219 to about 1240 comprise the cytoplasmic domain, see Para [0031]. Vilalta explicitly suggests that removal of residues comprising the transmembrane domain and optionally, the cytoplasmic domain, results in a soluble protein that can be used in vaccine compositions [0031]. Vilalta also teaches use of the polypeptide of SEQ ID NO: 2 in a method of raising the immune response to SRAS in a vertebrate, see Abstract.

19. Vilalta does not explicitly teach a polypeptide **consisting of** amino acids 1-1193 of S protein. Vilalta's S polypeptide of SEQ ID NO: 2 is only three amino acids longer

than the claimed polypeptide **consisting of** amino acids 1-1193 of S protein.

20. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a polypeptide consisting of amino acids 1-1193 of S peptide as an alternative or equivalent immunogenic composition as taught by Vilalta. The skilled artisan would have been motivated to do so, and would have a reasonable expectation of success, given Valalta's teachings that an S polypeptide comprising amino acids 1 to about 1195 of S protein comprise a soluble peptide, which can be used as vaccine composition. One of ordinary skill in the art would expect that the claimed S peptide would have the same function and property as the S polypeptide of SEQ ID NO: 2 of the prior art, given that the claimed S peptide has substantially the same sequence as S polypeptide of SEQ ID NO: 2 of the prior art. The three-amino acid size difference between the prior art peptide and the claimed peptide appears to be a design choice. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Remarks

21. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/BO PENG/
Examiner, Art Unit 1648